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Cato Laurencin, MD, PhD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DRE-0067
Inventors: Laurencin et al.
Serial No.: 10/052,121
Filing Date: January 17, 2002
Examiner: Naff, David M.
Customer No.: 26259
Group Art Unit: 1651
Confirmation No.: 1682
Title: Biocompatible, Biodegradable
Polymer-Based Lighter Than or
Light as Water Scaffolds for
Tissue Engineering and Methods for
Preparation and Use Thereof

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Declaration by Dr. Cato T. Laurencin, M.D., Ph.D.

I, Cato T. Laurencin, hereby declare:

1. I am a co-inventor of the above-referenced patent application.
2. I am also a co-author of the paper of Devin et al. entitled "Three-dimensional degradable porous polymer-ceramic matrices for use in bone repair" which published in 1996 in J. Biomater. Sci. Polymer Edn. Volume 7, Number 8, pages 661-669. The matrix described in this paper was prepared in my laboratory under my supervision and thus, I am extremely familiar with the data and Figures provided therein.
3. The matrix described in the 1996 paper of Devin et al. was made up of an aggregate of solid polymer

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microspheres. Porosity in the matrix resulted from imperfect packing of the solid polymer microspheres and leaching of the salt added during preparation of the matrix. This leaching resulted in pores or channels between aggregates of the solid microspheres.

4. A pore or channel running through our matrix resulting from imperfect packing of the solid microspheres and/or the salt leaching process is shown in the ESEM photograph of Figure 2. The dark circular areas represent channels or pores while the white areas are aggregates of solid microspheres. A different view of the channel or pore extending through the matrix between aggregates of solid microspheres is shown in Figure 3 of the 1996 paper. The ESEM photograph shown in Figure 4 of the 1996 paper provides what I consider to be the best picture of a single solid microsphere of that matrix. I am providing a copy of the ESEM photograph of Figure 4 herewith with the solid microsphere circled for clarity. This solid microsphere is completely different to the hollow microcarriers described in the above-referenced patent application.

I hereby declare that all statements herein of my own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful statements and the like so made are punishable by fine or by imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application, any patent issuing there upon, or any patent to which this verified statement is directed.


Cato T. Laurencin6/6/05
Date